HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

M2983N

August 27, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert W. Blazer, President
The Dekalb Farmers Market
3000 East Ponce De Leon Avenue
Decatur, GA 30031

Warning Letter

Dear Mr. Blazer:

On April 20 & 22, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant located at Decatur, Georgia. Our investigators documented deviations from FDA's seafood importing regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause the seafood products imported by your firm, including raw peeled-and-deveined frozen shrimp, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), as follows:

> Failure to take any of the affirmative steps described under 21 CFR 123.12(a)(2)(ii) to ensure that the fish and/or fishery products, including raw frozen shrimp, imported by your firm have been processed in accordance with the seafood HACCP regulations. Although Frank Valesquez, Seafood Support Manager, had stated that your firm would implement affirmative step (D), as described under 21 CFR 123.12(a)(2)(ii), our investigators found otherwise. Specifically, the foreign supplier's HACCP plan for raw frozen shrimp had not been corrected, and there was no written guarantee on record, from the foreign processor, that the frozen shrimp had been processed in accordance with the seafood HACCP regulations.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products

without examination until your firm is fully in compliance with the Seafood HACCP regulation.

Please notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

During the inspection, our investigators reviewed your firm's implementation of the seafood processing regulations applicable to your domestic operation. They observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. The FDA investigators also provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501), and the 483, which present their evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

1. Failure to develop and implement a HACCP plan as required by 21 CFR 123.6 to address the species related hazard of ciguatera fish poison (CFP) associated with the raw whole snapper (*Lutjanus spp.*) processed by your firm. You or your designee must also determine through a hazard analysis whether there are food safety hazards that are reasonably likely to occur for the other seafood products processed and/or stored by your firm. If so, a HACCP plan should be developed and implemented to control those hazards.

2. Evaluation of your plant sanitation found failure to monitor sanitation in accordance with 21 CFR 123.11(b). Your firm is required to monitor eight different areas of sanitation as they apply to your firm. 21 CFR 123.11(c) lays out the record keeping requirements for sanitation monitoring and corrections as a result of sanitation monitoring.

We encourage you to make the necessary improvements as soon as possible.

Your written reply should be directed to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309.

Sincerely,

Barbara A. Wood

for Ballard H. Graham, Director
Atlanta District